



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Tuesday, May 24, 2016

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 88049-2
DP Barcode: D432810
Product Name: 2.2% Sodium Hypochlorite Solution

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Demson Fuller, PM 32/ Donna Kamarei
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Ameriplus, Inc.

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s)</u>	<u>% by wt.</u>
014703	Sodium hypochlorite	2.2
	<u>Other Ingredient(s)</u> :	97.8
	Total:	100.0

- I BACKGROUND: Ameriplus, Inc. has submitted two new acute toxicity studies to support a labeling/ Signal Word change for "2.2% Sodium Hypochlorite Solution". Product Safety Labs conducted these eye and skin irritation studies.

The Chemistry and Toxicology Team (CTT) conducted an acute toxicity review of 88049-2 on 5/6/2011. The results of that review were:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	48359803	IV	Acceptable
Acute Dermal Toxicity	48359804	IV	Acceptable
Acute Inhalation Toxicity	48359805	IV	Acceptable
Primary Eye Irritation	None	I	Waiver
Primary Skin Irritation	48359806	I	Acceptable
Dermal Sensitization	48359807	Nonsensitizer	Acceptable

II RECOMMENDATIONS:

1. Each of the six studies is acceptable.

The acute toxicity profile for Registration Number 88049-2 is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	48359803	IV	Acceptable
Acute Dermal Toxicity	48359804	IV	Acceptable
Acute Inhalation Toxicity	48359805	IV	Acceptable
Primary Eye Irritation	49864401	IV	Acceptable
Primary Skin Irritation	49864402	III	Acceptable
Dermal Sensitization	48359807	Nonsensitizer	Acceptable

III LABELING:

1. CTT changes the Signal Word to "CAUTION".

2. The Precautionary Statements must state:

“Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.”

3. The First Aid statement must state:

If on Skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

4. The registrants may use toxicity category III precautionary statements and/or First Aid statements if they wish.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 32
MRID No.: 49864401

Reviewer: I. Blackwell
Study Completion Date: 2/25/2016
Lab Study No.: 42520

Testing Laboratory: Product Safety Labs
Author(s): Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: 2.2% Sodium Hypochlorite Solution, Reg. No. 88049-2
Dosage: 0.1 mL

Species: New Zealand Albino rabbit **Sex:** 3 females
Weight: 2107-2388 g **Age:** 12 weeks
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Procedure (Deviations From §81-4): none

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	0/3	---	---	---
Iritis	0/3	0/3	0/3	0/3	0/3	---	---	---
Conjunctivae								
Redness	0/3	0/3	0/3	0/3	0/3	---	---	---
Chemosis	3/3	1/3	0/3	0/3	0/3	---	---	---
Discharge	0/3	0/3	0/3	0/3	0/3	---	---	---

--- = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 32

MRID No.: 49864402

Reviewer: I. Blackwell

Study Completion Date: 2/25/2016

Lab Study No.: 42521

Testing Laboratory: Product Safety Labs

Study Director: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: 2.2% Sodium Hypochlorite Solution, Reg. No. 88049-2, pH 11.5-12.5

Dosage: 0.5 mL

Species: New Zealand Albino rabbit

Weight: 2233-2367 g

Age: 12 weeks

Source: Robinson Services, Inc.

Summary:

1. Toxicity Category: III
2. Classification: Acceptable

Procedure (Deviations From §81-5):

Results: One hour after exposure, 1/3 animals displayed moderate-to-severe erythema, 2/3 very slight erythema and 3/3 had slight edema. Twenty-four hours after exposure, 1/3 animals had severe erythema, 1/3 moderate-to-severe erythema and 1/3 very slight erythema. Forty-eight hours after exposure, 1/3 animals had severe erythema, 2/3 moderate-to-severe erythema, 3/3 had no edema. Seventy-two hours after the exposure to the test material, 3/3 animals displayed moderate erythema with no edema. Seven and ten days after exposure, 1/3 animals displayed very slight erythema with or without desquamation and small areas of eschar.

Special Comments: None